REMARKS

The Office Action of October 30, 2006 has been carefully reviewed and this paper is responsive thereto. Claims 1-13 and 15-43 are pending. Claim 14 is cancelled. Claims 1-43 stand rejected. By this response, claims 1-3, 6-7, 14-16, 23-24, 28-32, 40 and 43 have been amended. No new matter has been introduced into the application.

Amendments to the Specification

Applicants have amended paragraphs 56, 65, 66, 68, 73, 76, 77, 78, 100, 101 and 109 of the specification to describe the labels depicted in the Figures as filed so as to be in compliance with 37 C.F.R. 1.121(b) as requested by the Office Action. Figure 117 was amended to correct a typographical error. In addition, paragraphs 104 and 106 of the specification have been amended to correct typographical errors associated with the reference to steps not shown in Figures 20 and 21 so as to better correspond to the subject depicted in these Figures. No new matter was added by these amendments and entry of same is respectfully requested.

Objections to the Drawings

The drawings were objected for showing labels not references in the specification. As noted above, Figure 12 has been amended. In addition, the specification has been amended to use the labels shown in the Figures. Accordingly, this ground for rejection is believed obviated.

Cancelled Claim

Claim 14 was cancelled without prejudice or disclaimer and Applicants reserve the right to file a similar claim in a continuation application. Thus, the rejection of claim 14 is considered moot.

Amended Claims

Claims 1-3, 6-7, 14-16, 23-24, 28-32, 40 and 43 were amended to clarify the intended scope of each respective claim.

Claim 1 was amended to address the Office Action's concerns regarding the use of the phrase "meaningfully" and now recites, in relevant part:

(d) blanking the neurological signal during the first time interval of time;

(e) blanking the neurological signal during a second time interval that extends beyond the first time interval, wherein the neurological signal is adversely affected by the delivering of treatment therapy in (c) the first time interval during the second time interval;

(f) processing the neurological signal during a third time interval corresponding to a detection window; and

(g) after the third interval, determining whether to redeliver the treatment therapy using an algorithm output based on the processing in (f).

To the extent support for this amendment is not inherent in the claim as filed, support for the amendment is at least found in the specification as filed, starting on pg. 49, in ¶ 147-150. Thus, no new matter was added

Claim 2 was amended to recite:

The method of claim 1, wherein the determining in (g) comprises:

(i) processing the neurological signal for sufficient time to provide statistical analysis regarding efficacy of the treatment therapy.

To the extent support for this amendment was not inherent in the claim as filed, support is at least found in the specification as filed on pg. 49, ¶ 149. Thus, no new matter was added.

Claim 3 was amended to recite:

The method of claim 2, wherein the determining in (g) further comprises:

(ii) determining whether a maximum ratio is above a predetermined threshold.

Support for this amendment is at least found in the specification as filed on pg. 50, ¶ 149, thus no new matter was added.

Claims 6 and 7 were amended to provide better antecedent basis for the recited time intervals. Claims 15, 16, 23 and 24 were amended so as to better claim the disclosed subject matter. Claims 29-32 were amended to recite a "predetermined number" so as to further clarify the intended scope.

Claim 40 was amended to address the Office Action's concerns regarding the use of the phrase "meaningfully" and now recites, in relevant part:

(d) blanking the neurological signal during the first time interval of time;

(e) blanking the neurological signal during a second time interval that ends after the first time interval ends, wherein the neurological signal is affected by a signal artifact and wherein the amplifier is stabilizing during the second time interval;

(f) processing the neurological signal during a third time interval in order to stabilize the detection algorithm; and

(g) in response to (e), processing the neurological signal for a fourth time interval that is sufficient to provide statistical analysis regarding efficacy of the treatment therapy.

To the extent support for this amendment was not inherent in the claim as filed, support is at least found in the specification as filed, starting on pg. 49, in ¶ 147-150. Thus, no new matter was added.

Claim 43 was amended to address the Office Action's concerns regarding the use of the phrase "meaningfully" and now recites, in relevant part:

(d) blanking the neurological signal during the delivery of the therapy;
(e) blanking the neurological signal for an additional time interval after a termination of the delivery of therapy to allow for amplifier recovery; and
(f) resuming processing of the neurological signal immediately after completion of (d) and (e) for a further interval of time sufficient to stabilize the detection algorithm.

To the extent support for this amendment was not inherent in the claim as filed, support is at least found in the specification as filed, pg. 49, in ¶ 147-149. Thus, no new matter was added.

In view of the support provided in the specification, no new matter has been added to the amended claims and entry of these amendments is requested.

Rejections under 35 U.S.C. § 112

The Office Action rejected the pending claims under 35 U.S.C. § 112 as being indefinite. The various grounds of rejections will be addressed in turn, however Applicants respectfully disagree with the suggestion that the claims were indefinite and note that many of the alleged reasons for the claims being indefinite do not comport with accepted patent practice. Furthermore, it appears that there is confusion regarding breadth of scope versus definiteness and it is noted that terms that have a broad definition are not therefore indefinite.

Regarding the term "detection cluster," this term is used in the specification in a number of places. In paragraph 106, pg. 33, the specification explains that a seizure may be a detection cluster. The specification further explains how detection clusters are determined:

> A medical device system, e.g., external system 100, determines detection clusters using a temporal criterion, based on the distributions of durations of ictal discontinuities or interictal time intervals. Detections that are separated in time by a programmable inter-detection interval are assigned to the same cluster unit and deemed as being part of the same seizure as shown in Figure 22.

Specification as filed, pg. 39, ¶ 120. Paragraphs 121-123 provided further explanation of how a detection cluster may begin and end. In view of the disclosure, Applicants respectfully submit that a person of skill in the art would understand what a detection cluster is, as well as how it may begin and end. Accordingly, a person of skill in the art would understand the scope of the term "detection cluster" as used in the claims and the use of the term "detection cluster" does not make the claims indefinite.

Regarding the use of the term "meaningfully" it is noted that relative terms are perfectly permissible. However, to expedite prosecution this term is no longer being used in the pending claims.

Regarding the use of the terms "blanking hardware" and "blanking software," Applicants submit that these terms are broadly directed to concept of blanking signals, which is known in the art, with either hardware or software. It is respectfully submitted that a person of skill in the art would understand how to blank a signal with hardware (for example, with a circuit that disconnects the signal) and software (which could ignore the signal) and therefore would understand the scope of these terms. Accordingly, these terms do not make the claims indefinite.

Regarding the use of the term "approximately" in claims 17-19, Applicants note that the use of a relative term does not make the phrase indefinite. For example, a recent search of issued U.S. Patents from 1976 turned up the use of "approximately" in the claims of almost 200,000 patents. In addition, it is a long standing practice to use a phrase such as "approximately" when providing a numerical range, see claim 6 of U.S. Patent No. 7,168,048 for example. Thus, such use is well accepted and the Office Action's arguments are contrary to a number of precedential opinions by Court of Appeal for the Federal Circuit. *See e.g., Hilton Davis Chemical Co. v. Warner-Jenkinson Co., Inc.*, 114 F.3d 1161, 1164 (Fed. Cir. 1997) (accepting the use of the phrase "from approximately 6.0 to 9.0" in a patent claim after remand from the Supreme Court of the United States).

Regarding the use of the terms "short-term" and "long-term," the specification explains:

> (The ratio of an EEG waveform at a given time is the largest ratio of a short-term value (foreground) divided by a long-term value (background) over a set of neurological signals or channels. (A short-term value or a long-term value may be an average value, a median value, or some other statistical measure.) In the embodiment, the short-term value spans the previous 2 seconds of EEG data, and

> the long-term value spans the previous 30 minutes or more. Other embodiments may use short-term and long-term values spanning different time durations.)

Specification as filed, pg. 40, ¶ 121. In view of this discussion that provides examples of what a long-term and a short-term value can be, Applicants respectfully submit that a person of skill in the art could ascertain the scope of the invention and, therefore, the use of these terms does not cause the claims to be indefinite.

Regarding the use of the term "maximum ratio," the specification as filed explains that:

> Maximal ratio 2203 (for a given instant in time) is determined from a waveform frame 2251 by identifying an EEG waveform (2253, 2255, 2257, or 2259) having the largest ratio at the given instant in time. (The ratio of an EEG waveform at a given time is the largest ratio of a short-term value (foreground) divided by a long-term value (background) over a set of neurological signals or channels.

Specification as filed, pg. 40, ¶ 121. In view of this discussion, Applicants respectfully submit that a person of skill in the art would be able to ascertain the scope of this term, and, therefore, the use of this term does not cause the claims to be indefinite.

Regarding the use of the phrase "first number", Applicants respectfully submit such convention is common and proper. However, to avoid any confusion in claims 30-32, claims 29-32 have been amended to recite "predetermined number," thus obviating this reason for rejecting these claims.

Regarding the use of the term "treatment therapy unit" in claim 40, the specification as filed implicitly explains that treatment therapy units may be external, implantable or a hybrid:

> Disclosed herein are three general embodiments of the medical device system – an external system, a hybrid system, and an implanted system – however, the invention may be embodied in any number of configurations. The following embodiments may be described with the specific application of treating epilepsy by electrical stimulation of the brain and using closed-loop control monitoring of electrical activity in the brain. Other embodiments of the invention may use open-loop therapy, namely treatment therapy that can be provided independent of information obtained from the monitoring of brain activity. It will be appreciated, however, that other embodiments of the invention may treat other nervous system disorders, utilize other treatment therapies, optionally utilize closed-loop feedback control by receiving other forms of neurological signals, and/or deliver therapeutic treatment to neural tissue in other locations in the body.

Specification as filed, pg. 7-8, ¶ 41. In addition, examples of embodiments of therapy treatment units are depicted in Figures 1, 9 and 12. Accordingly, Applicants respectfully submit a person

of skill in the art, in view of the specification as filed, would understand the scope of the phrase as recited in the claim. Therefore, the use of this term does not cause this claim to be indefinite.

In view of the above amendments and indications of support for the various phrases, withdrawal of this ground of rejection is respectfully requested.

Rejection under 35 USC §102 – Fischell

Claims 1-13 and 15- 43 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,016,449 to Fischell *et al.* ("Fischell"). Claims 1, 40 and 43 are independent.

Looking at claim 1, the feature "blanking the neurological signal during a second time interval that extends beyond the first time interval, wherein the neurological signal is adversely affected by the delivering of treatment therapy in (c) the first time interval during the second time interval" is recited. Applicants have reviewed the disclosure of Fischell and have been unable to locate any mention of such a blanking. Rather, Fischell merely discloses blanking during the delivery of stimulation. *See e.g.,* Fischell, Col. 13, Ln. 52-55. Therefore, as Fischell fails to disclose such a feature, Fischell cannot be said to anticipate claim 1.

Claims 2-13 and 15-39 directly or indirectly depend from claim 1 and thus necessarily include the above feature that is recited in claim 1. Therefore, claims 2-13 and 15-39 are not anticipated for at least the reason that claim 1 is not anticipated and for the additional features recited therein.

Claim 40 recites the feature "blanking the neurological signal during a second time interval that ends after the first time interval ends, wherein the neurological signal is affected by a signal artifact and wherein the amplifier is stabilizing during the second time interval." While Fischell discloses blanking during stimulation delivery, Fischell fails to disclose any blanking after the stimulation has been delivered, let alone as recited in Figure 40. Therefore, Fischell fails to disclose all the feature of claim 40 and cannot be said to anticipate claim 40 for at least this reason.

Claims 41-42 depend from claim 40 and thus necessarily include the above feature that is recited in claim 40. Therefore, claims 41-42 are not anticipated for at least the reasons that claim 40 is not anticipated and for the additional features recited therein.

Claim 43 recites the feature "blanking the neurological signal for an additional time interval after a termination of the delivery of therapy to allow for amplifier recovery." While

Fischell may disclose blanking, there is no suggestion of blanking after "after a termination of the delivery of therapy" as recited in claim 43. Therefore, as Fischell fails to disclose such a feature, Fischell cannot be said to anticipate claim 43.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

CONCLUSION

Applicants respectfully request consideration of the pending claims and a finding of their allowability. A notice to this effect is respectfully requested. Please feel free to contact the undersigned should any questions arise with respect to this case that may be addressed by telephone.

Respectfully submitted,

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